



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,023	11/16/2001	Peter Madsen	6258.200-US	2060

7590

10/11/2002

Reza Green, Esq.
Novo Nordisk of North America, Inc.
Suite 6400
405 Lexington Avenue
New York, NY 10174-6401

EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 10/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
--------------------	-------------	-----------------------	------------------

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

9

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on July 22, 2002
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~which is~~ whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 2, 4, 5 and 19-36 are pending in the application.
- ☐ Of the above, claim(s) 19-34 are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 2, 4, 5, 35 and 36 are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☒ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5 and 7
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

09/996, 02

DETAILED ACTION

Claims 1, 2, 4, 5 and 19-36 are pending in the application.

Election/Restrictions

Applicants' election of Group I in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in Paper No. 8.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

Claims 5, 35 and 36 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 2, commas or semi-colons should be added after each compound listed. Also in claims 1 and 2, an "and" should be added before the last compound listed. In claim 1, "sulfonyl" is misspelled in several instances (e.g. page 60, lines 39, 42, 45, etc.).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 5, 35 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 13, 16-18, 22, 23, 43-46, 49, 53, 55-57, 59, 63, 68-71, 89, 90, 93, 94, 98, 100-114, 116 and 118 of copending Application No. 09/572,553. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims in 09/572,553 differ only by generic description, or an overlap between the subject matter being claimed. Note, claims 57, 63, 94, 98, 100, 101 and 113 in 09/572,553. Especially note the compound in claim 1 on page 61, lines 19-20 in the instant application and Example 265 in 09/572,553.

The indiscriminate selection of "some" among "many" is *prima facie* obvious. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g. a glucagon antagonist). One skilled in the art would thus be motivated to prepare compounds embraced by 09/572,553 to arrive at the instant claimed compounds with the expectation of obtaining

additional beneficial compounds which would be useful in treating, for example, obesity. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, 35 and 36 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/572,553 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending

application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

Applicants claim glucagon antagonists. 09/572,553 teach glucagon antagonists which are structurally similar to the instant claimed compounds. The difference between the instant claims and the teaching in 09/572,553 is that there is an overlap between the subject matter being claimed. Note, claims 57, 63, 94, 98, 100, 101 and 113 in 09/572,553. Especially note the compound in claim 1 on page 61, lines 25-26 in 09/572,553. 19-20 in the instant application and Example 265 in 09/572,553.

The indiscriminate selection of “some” among “many” is *prima facie* obvious. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g. a glucagon antagonist). One skilled in the art would thus be motivated to prepare compounds embraced by 09/572,553 to arrive at the instant claimed compounds with the expectation of obtaining

additional beneficial compounds which would be useful in treating, for example, obesity. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(1)(1) and § 706.02(1)(2).

Claims 1, 2, 4, 5, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over 09/572,553.

Applicants claim glucagon antagonists. 09/572,553 teaches glucagon antagonists which are structurally similar to the instant claimed compounds. The difference between the instant claims and the teaching in 09/572,553 is that there is an overlap between the subject matter being claimed. Note, claims 57, 63, 94, 98, 100, 101 and 113 in 09/572,553. Especially note the compound in claim 1 on page 61, lines 19-20 in the instant application and Example 265 in 09/572,553.

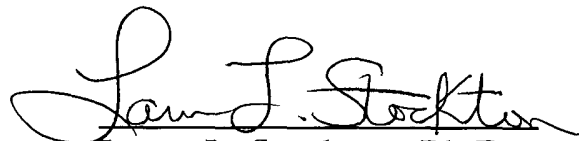
The indiscriminate selection of “some” among “many” is *prima facie* obvious. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g. a glucagon antagonist). One skilled in the art would thus be motivated to prepare compounds embraced by 09/572,553 to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating, for

example, obesity. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

A handwritten signature in cursive script, reading "Laura L. Stockton". The signature is written in black ink and is positioned above the printed name and title.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

October 8, 2002